VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 01/15/08

Board Members:

Michael Scovner, M.D., Chair	Norman Ward, M.D.	Lynne Vezina, R.Ph.
Andrew Miller, R. Ph.	Kathleen Boland, Pharm.D.	Frank Landry, M.D.
Richard Harvie, R. Ph.	Virginia Hood, M.D.	Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA	Nancy Miner, (MHP)	Erin Cody, M.D., OVHA
Diane Neal, R.Ph., (MHP)	Stacey Baker, OVHA	Judy Jamieson, OVHA
Robin Farnsworth, OVHA	Jennifer Mullikin, OVHA	

Guests:

Adam Kopp, Shire	James Kokoszyna, Allergan	Mark Walker, Shire
Amy Finn, Merck	James Soriano, Shire	Michael Deorsey, Abbott
Carl Marchand, AstraZeneca	Joe Winalski, Biogen Idec	Nate Capone, Shire
Carl Pepe, GSK	Keith White, Genentech	Scott Mosher, GSK
Caroline Decota, Healthpoint	Kenneth Brown, Shire	Steven Berardino, Amgen
David Anderson, AstraZeneca	Linda Barton, Pfizer	Tracy Bernasconi, AstraZeneca
Glenn E. Dooley, Sr, Sanofi-Aventis	Lyndon Braun, Santarus	Vince Matteo, Eli Lily

Michael Scovner, M.D. Chair, called the meeting to order at 7:02 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The December 2007 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Catamount Enrollment: There are over 1000 beneficiaries enrolled to date. There are discussions ongoing about whether employers might be able to buy into this coverage in the future.

4. Medical Director Update: *Erin Cody, M.D., OVHA*

Clinical Programs Update: No updates to report.

Prescriber Comments: An email comment regarding Lyrica® was received from a prescriber and will be discussed later in the meeting.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Diabetic Testing Supplies:
  Communications regarding the changes in preferred diabetic testing supplies were shared with the DUR Board. A letter describing the changes in coverage was sent to pharmacies in December. A mailing was sent to prescribers and pharmacies in the second week of January with more detailed information. Following that a mailing was sent to each beneficiary who was identified as using a non-preferred test strip. Beneficiaries were encouraged to discuss meter choices with their pharmacists but were also given toll free phone numbers to use if they wished.

- OVHA Pharmacy Bulletin: Buprenorphine PA Process, Diabetic Testing Supply PDL Changes:
  A December issue of the OVHA Pharmacy Bulletin discussed the diabetic testing supply PDL changes as well as the new prior authorization criteria for Suboxone® and Subutex®.

- CellCept®/Myfortic® Communication to Prescribers:
  A patient specific mailing was sent to prescribers of CellCept® and Myfortic® reinforcing the need for contraceptive counseling for female patients on these medications.

- Erythropoiesis Stimulating Agents Communiction to Prescribers (and new FDA News Release – Risk of Anemia Drugs):
  An additional FDA news release discussed 2 further studies that showed tumor growth and increased mortality in cancer patients receiving these agents. This information will be combined with that from an earlier FDA communication and a letter will be sent out to all recent prescribers of these agents.

- OVHA Pharmacy Bulletin: Summary of PDL Changes for 01/01/08:
  An early January issue of the OVHA Pharmacy Bulletin summarized all the 1/1/08 PDL changes.

- FDA News - Compounded Menopause Hormone Therapy Drugs:
  The FDA sent warning letters to a number of pharmacies that make claims regarding the safety and efficacy of "bio-identical hormone replacement therapy". The FDA is concerned that these unfounded claims mislead women and health care professionals.

Public Comment: No public comment.

Board Decision: None needed.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Neupro® Patch (rotigotine) - Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication is Parkinson's disease and the prescriber provides medical necessity for the transdermal formulation (e.g. swallowing disorder, difficulty taking oral medications or difficulty with compliance of multiple daily doses of an oral dopamine agonist). A quantity limit of one patch/day was recommended.

Public Comment: No public comment

Board Decision: The Board approved the MHP recommendations as described.

- Seroquel® XR (quetiapine) - Not recommended for addition to the PDL. A quantity limit of one tablet/day was recommended for the 200 mg tablet only. A discussion ensued on the appropriate criteria for coverage.

Public Comment: Tracy Bernasconi, AstraZeneca – Commented on the streamlined once daily dosing of Seroquel® XR.

Board Decision: The Board approved the MHP recommendations noted above with the criteria for coverage being that the patient is not adherent to twice daily dosing of immediate release Seroquel® resulting in a significant clinical impact.

- Vyvanse® (lisdexamfetamine) - Recommended for addition to the PDL. A quantity limit of one capsule per day is recommended as well as prior authorization being required for children less than 3 years old (standard with all CNS stimulants).

Public Comment: Kenneth Brown, M.D., Shire – Discussed his clinical experience with Vyvanse®.

Board Decision: The Board approved the MHP recommendations as described.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)* (Public comment prior to Board action)

Criteria Changes

- Anticonvulsants (Lyrica® in fibromyalgia):
  It was recommended that Lyrica® remain as PA required with automated step therapy for the indication of fibromyalgia. The recommended step therapy is that the patient has had a documented side effect, allergy, or treatment failure to BOTH of the following: gabapentin AND one of an antidepressant (TCA, SSRI, Novel) or cyclobenzaprine, if medication is being used for fibromyalgia. The quantity limit would remain 3capsules/day.

Public Comment: Rup Tanden, M.D - submitted an email describing his professional experience with prescribing Lyrica® to patients with fibromyalgia.

Board Decision: The Board unanimously agreed that Lyrica® remain as PA required but requested that the clinical criteria for approval be modified to read the patient has had a documented side effect, allergy, or treatment failure to TWO drugs from the following: gabapentin, tricyclic antidepressant, SSRI antidepressant, novel antidepressant or cyclobenzaprine, if medication is being used for fibromyalgia.

- Anti-diabetics: Insulin:
  The criteria for PA requiring products were clarified so as to be more specific. A store brand insulin was recommended to be moved from preferred to PA required.

Public Comment: No public comment.

Board Decision: The updated table and revised criteria were unanimously accepted.

- Anti-Infectives: Influenza Vaccines:
  The criteria were updated to reflect the expanded FDA approved age range for FluMist® allowing children as young as 2 years to also receive this vaccine. Dosing information was also updated.

Public Comment: No public comment.

Board Decision: The updated criteria and dosing information were unanimously accepted.

- BPH: Androgen Hormone Inhibitors:
  Criteria were developed for males less than 45 years old (a diagnosis of BPH). Coverage of androgen hormone inhibitors will not be approved for cosmetic use (male-pattern baldness/alopecia or hirsutism). Quantity limits of 1 tablet or capsule per day were recommended for all products in this class.

Public Comment: No public comment.

Board Decision: The Board approved the clinical criteria, limitations to coverage and quantity limits as recommended.

- Cough and Cold Preparations:
  Specific criteria were proposed for approval of Tussionex® and other branded preparations. For approval of Tussionex the patient has had a documented side effect, allergy, or treatment failure to two of the following generically available cough and cold products: hydrocodone/homatropine (compare to Hycodan®), hydrocodone/guaifenesin (compare to Hycotuss®), promethazine/codeine (previously Phenergan® with Codeine), hydrocodone/chlorpheniramine/pseudoephedrine (compare to Hydron PSC®) or hydrocodone/pyrilamine/phenylephrine. For approval of other branded products the prescriber must provide a clinically valid reason for the use of the requested medication including reasons why any of the generically available preparations would not be a suitable alternative.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Pulmonary: Antihistamines: 1st Generation:
  Criteria for approval of non-preferred products were proposed as the prescriber must provide a clinically valid reason for the use of the requested medication including reasons why any of the generically available products would not be a suitable alternative.

Public Comment: No public comment.

Board Decision: The clinical criteria were unanimously approved.

Preferred Product Changes

- Anti-hyperkinesis and Anti-Narcolepsy (and quantity limits):
  Requests for prior authorization for Daytrana® were reviewed and found to be generally appropriate. It was recommended that Daytrana® be moved to preferred status. The Board supported reviewing this category for need of quantity limits.

Public Comment: No public comment.

Board Decision: The Board approved moving Daytrana® to preferred status.

- Anti-Infectives: Genital Antivirals:
  Deferred until next meeting.

8. New Drug Classes: *Diane Neal, R.Ph, (MHP)*

- Gastrointestinals: Inflammatory Bowel Agents:
  A therapeutic class review of oral and rectal mesalamine products was presented. It was recommended that Asacol®, Pentasa® and Lialda® oral be designated as preferred products. Canasa® suppositories and generic mesalamine enema would also be preferred. Brand Rowasa® mesalamine enema would be PA required.

Public Comment: No public comment.

Board Decision: The preferred and PA requiring products were unanimously accepted as presented.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Marinol®
  The prior authorization criteria for dronabinol were implemented on June 1, 2007. Data assessment for the 5 months prior to the dronabinol prior authorization implementation and the 5 months following the prior authorization implementation was conducted. The results showed a decrease in the number of unique utilizers, number of paid claims, and the paid amounts during the 5 months following implementation. There was a 48% decrease in the cost of paid claims for dronabinol. A review of all prior authorization requests was conducted to determine appropriateness of the prior authorization criteria and indications. Overall, dronabinol requests were approved for appropriate indications and patients had adequate trials to meet prior authorization criteria. All prior authorization approvals for non-FDA approved indications were given when deemed medically necessary. All denials were also appropriate and the prior authorization process limited inappropriate usage of dronabinol. Based on the review of prior authorization requests and claims data, it is recommended that dronabinol remain on prior authorization with the criteria unchanged.

Public Comment: No public comment.

Board Decision: The Board agreed with the drug utilization review and the recommendation to leave the criteria unchanged.

- Mental Health Medication Use in Children:
  A further breakdown of the mental health medication use in children that was presented at last month's meeting was discussed. A summary of prescriber specialty was presented as well as the recipient age for those in the 0 - 6 age group. The information presented will be shared with the Vermont Association for Mental Health, the Vermont Department of Mental Health and the American Board of Pediatrics in the state.

Public Comment: No public comment.

Board Decision: None needed.

10. New Drug Product Plan Exclusions (Consent agenda topic): *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 12/06/07 - 12/20/07. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: The Board approved the products to be blocked.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Desmopressin Acetate – severe hyponatremia and seizures: The FDA notified healthcare professionals and patients of the Agency's request that manufacturers update the prescribing information for desmopressin to include important new safety information about severe hyponatremia and seizures. Certain patients, including children treated with the intranasal formulation of the drug for primary nocturnal enuresis (PNE), are at risk for developing severe hyponatremia. As such, desmopressin intranasal formulations are no longer indicated for the treatment of primary nocturnal enuresis. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations and asked that coding be changed to require PA for patients less than 18 years old to ensure that the nasal formulation is not being used for primary nocturnal enuresis.

- Fentanyl Transdermal System – death and overdose: The FDA issued an update that highlights important information on appropriate prescribing, dose selection, and the safe use of the fentanyl transdermal system (patch). The Agency continues to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The update will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations and suggested that the information be included in the next clinical issue of the OVHA Pharmacy bulletin.

- Bisphosphonates – severe bone, joint and/or muscle pain: The FDA informed healthcare professionals and patients of the possibility of severe and sometimes incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates. The association between bisphosphonates and severe musculoskeletal pain may be overlooked by healthcare professionals, delaying diagnosis, prolonging pain and/or impairment, and necessitating the use of analgesics. The recommendation is that no action is required on the part of the DUR Board in response to this communication. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

13. Adjourn: Meeting adjourned at 9:22 p.m.

Next DUR Board Meeting
Tuesday, February 12, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.